July 15, 2008

Alan Taylor
Regulatory Compliance
Chemtura Corporation
Benson Road 2-19
Middlebury, CT 06749

Dear Dr. Taylor:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the revised test plan for phosphorus acid, triphenyl ester, reaction products with dipropylene glycol, posted on the ChemRTK HPV Challenge Program Web site on March 1, 2007. I commend Chemtura Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site (http://www.epa.gov/chemrtk/guidocs.htm/), EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. EPA encourages Chemtura to move quickly to enhance this test plan and to complete a final package. EPA has moved energetically from the HPV Challenge Program to the Chemical Assessment and Management Program (ChAMP: www.epa.gov/champ) and is relying on Challenge chemical sponsors to provide, as expeditiously as possible, the data that are the key to this effort.

Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov. If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Phosphorus acid, triphenyl ester, reaction products with dipropylene glycol

Summary OF EPA Comments

The sponsor, Chemtura Corporation, submitted a revised test plan and robust summaries to EPA for Phosphorus acid, triphenyl ester, reaction products with dipropylene glycol (CAS No. 116265-68-0), dated November 10, 2006. EPA posted the submission on the ChemRTK HPV Challenge Web site on March 1, 2007. Data for two analogs, Weston DHOP and THOP (including poly(dipropyleneglycol) phenyl phosphite, CAS No. 80584-86-7 -- named incorrectly in the submission) and Weston PTP (including heptakis(dipropyleneglycol) triphosphite, CAS No. 13474-96-9) were also submitted.

EPA has reviewed the submission and has reached the following conclusions:

1. Supporting Chemicals Justification. The submitter needs to address various issues related to the proposed supporting chemicals.

2. Physical chemical properties. EPA agrees with most of the proposed testing for these endpoints. The complex nature of the substance makes determination of a useful measured melting point unlikely.

3. Environmental Fate. EPA agrees with the submitter's test plan to provide stability in water and biodegradation data according to OECD guidelines. Photodegradation data are needed for an additional representative structure. The submitter needs to recalculate its fugacity values using any new measured physicochemical values.

4. Health and Ecological Effects. The submitter has proposed substantial testing for the sponsored chemical. EPA reserves judgment on the test plan until the submitter has clarified the composition of the sponsored substance.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments On The Phosphorus Acid, Triphenyl Ester, Reaction Products With Dipropylene Glycol Challenge Submission

Test Plan

General

The revised test plan still lacks a clear, readily understandable explanation of the nature of the sponsored substance and its relation to other substances cited in the test plan.

Substance Characterization

The test plan remains unclear about the chemical composition of the sponsored substance that would be used in the extensive proposed testing. Such information is important in evaluating both planned testing and test results. In response to EPA's preliminary comments on the original submission, the submitter has supplied additional information in Section 1.1 of the revised robust summaries. However, there is no clear statement of the range of structural composition of the sponsored substance, its average molecular weight, possible isomeric complications, etc. Not a single structural formula is provided. The name "poly(dipropylene glycol) phenyl phosphite" alone provides insufficient structural information. Nothing is said about the range of numbers of repeating units, whether this factor will vary significantly according to process variables or product properties requirements, and if so, how the variation is likely to affect the toxicological and other properties (examples of characterized mixtures are the submissions for rosin and rosin salts: http://www.epa.gov/chemrtk/pubs/summaries/rosnsalt/c13134tc.htm, or neo-acids C5-C28: http://www.epa.gov/chemrtk/pubs/summaries/neoc528/c13335tc.htm and fatty acid dimer and trimer:

http://www.epa.gov/chemrtk/pubs/summaries/ftadmrtr/c13651tc.htm. The hazard characterizations can be reviewed at the following link: http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report_by_cas?doctype=2).

The test plan states that the substance name "is intended to cover all the potential products derived from the reaction". The test plan needs to state what these potential products are in order to support an eventual hazard or risk characterization. Because the reaction yields a complex product, the test plan should discuss the reaction, its possible and known products including their structures, and what subsequent treatment leads to the cited commercial products Weston DHOP, Weston THOP, and Weston PTP.

In particular, in Robust Summary section 1.1.0, Weston THOP is characterized as 30-60% tetraphenyl dipropyleneglycol "diphosphate" (probably intended to be the diphosph*ite*), a monomer that would be at the low end of the spectrum of possible products and therefore an important component of the sponsored substance. However, it is impossible to determine from the submission whether this substance is a significant component of the sponsored substance. Heightening the confusion, the CAS number assigned by the submitter is for an oligomeric substance, not a monomer.

Supporting Chemicals Justification

The submitter appears to state that the two proposed supporting chemicals (CAS Nos. 80584-86-7 and 13474-96-9) are contained in commercial substances (Weston DHOP, THOP and PTP) that themselves are derived from the sponsored substance, and states that “Data from these potential products are relevant for the sponsored substance...” The mere assertion of relevance is inadequate for the purposes of the HPV Challenge Program. There is no structural comparison or other information presented to support a relationship to the sponsored chemical. In addition, the data provided show vastly different physicochemical properties (Table 2 in the Revised Test Plan) for these two substances and it is not clear which one (if either) would better represent the sponsored chemical.

There is much confusion in the submission as to the identity of the supporting chemical having CAS No. 80584-86-7. The substance is incorrectly named in the test plan and throughout the robust summaries as a phosphate rather than a phosphite. Only in robust summary section 1.1.0 is the substance properly named, but in the same paragraph the CAS No. is associated with two other names, both incorrect.

Although the supporting chemical data appear in the test plan sections on physical chemical properties, environmental fate, and health effects, it seems that the submitter plans to use the data only for acute toxicity. That being the case, and considering the differences in the data for the two substances, the problems cited above, and the likelihood that the repeated-dose study will provide acute toxicity data, the submitter should consider deleting the supporting chemical information from the test plan (using representative structures for modeling purposes remains appropriate).

Physical chemical properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The test plan states without elaboration that modeling can't be used to estimate these endpoints. While this might be true, any such statement needs to be explained, especially as such estimates do appear in the robust summaries.

The submitter proposes testing for all endpoints. EPA agrees with most of the proposed testing for these endpoints. Although the test plan makes contradictory statements about the need for melting point data, the complex nature of the substance makes determination of a useful melting point unlikely. Modeled melting point values for representative structures (see under Fugacity, below) are needed for the fugacity model.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

EPA agrees with the submitter's test plan to provide stability in water and biodegradation data according to OECD guidelines. Photodegradation modeling should include data for the lowest-molecular-weight significant component expected as well as a higher-molecular-weight species.

Fugacity. Modeling should include data for the lowest-molecular-weight significant component expected as well as a higher-molecular-weight species. The submitter needs to use as model inputs any relevant measured physicochemical values that are developed.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

EPA reserves judgment on the proposed test plan for the repeated-dose, genetic and reproductive/ developmental toxicity endpoints until the submitter has clarified the composition of the test substance. Acute toxicity data can be derived from dose-range finding studies used to conduct longer-term studies.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgment on the proposed test plan to perform acute aquatic toxicity tests in fish, invertebrates and green algae until the submitter has clarified the composition of the test substance.

Specific Comments on Robust Summaries

The robust summaries presented for the acute toxicity studies with the supporting substances lack sufficient detail to evaluate the information (e.g., number of animals used, doses used, whether any mortalities were observed, duration of observation period, etc.).

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.